DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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Memorandum

Date: JUN 29 2000

From: (Acting) Division Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling, and Dietary Supplements, HFS-820

Subject: 75-Day Premarket Notification for New Dietary Ingredients

To: Dockets Management Branch, HFA-305

New Dietary Ingredients:	*Acicarpha tribuloides* *Schkhuria pinnata* *Geranium filipes* *Mutisia acuminata* *Equisetum bogotense* *Stachys pusilla* *Bursera graveolens* *Chuquiraga spinosa* *Desmodium molliculum* *Oenothera rosea* *Perezia coerulescens* *Piper alveolatum* *Salvia sagittata* *Sanguisorba minor* *Satureja revoluta* *Tessaria integrifolia*
Firm:	Isula Rain, Inc.
Date Received by FDA:	April 21, 2000
90-Day Date:	July 19, 2000

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredients should be placed on public display in docket number 95S-0316 after July 19, 2000

Felicia B. Satchell

Felicia B. Satchell

95S-0316

RPT 71

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JUN 29 2000

Lawrence J. Brucia
President
Isula Rain, Incorporated
12 Skylark Drive, #31
Larkspur, California 94939

Dear Mr. Brucia:

This is in response to your letter to the Food and Drug Administration (FDA) dated April 21, 2000, making a submission for new dietary ingredients pursuant to 21 U.S.C. 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter notified FDA of your intent to market six dietary supplement products: Product #1, (7-Day Purity Cleanse #1 Extract Herbal Supplement), containing the new dietary ingredients *Equisetum bogotense* H.B.K., *Schkhuria pinnata* Lamarck, *Oenothera rosea* L'Her ex Aiton, and *Bursera graveolens* (H.B.K.) Triana & Planch, Product #2, (7-Day Digestive Cleanse #2 Extract Herbal Supplement), containing the new dietary ingredients *Mutisia acuminata* R. &P., *Schkhuria pinnata* Lamarck, *Tessaria integrifolia* R.&P., *Salvia sagittata* R.&P., *Equisetum bogotense* H.B.K, *Piper alveolatum* Opiz; Product #3, (7-Day Urinary Cleanse #3 Extract Herbal Supplement), containing the new dietary ingredients *Equisetum bogotense* H.B.K., *Acicarpha tribuloides* Jessieu, *Desmodium molliculum* H.B.K. DC, *Geranium filipes* Killip, *Stachys pusilla* (Wedd.) Briquet, *Chuquiraga spinosa* Lessing, *Satureja revoluta* R. &P.; Product #4, (GBDR Health Extract Herbal Supplement), containing the new dietary ingredients *Equisetum bogotense* H.B.K. and *Tessaria integrifolia* R. &P.; Product #5, (Muscle Joint Health Extract Herbal Supplement), containing the new dietary ingredients *Equisetum bogotense* H.B.K and *Satureja revoluta* R. &P.; and Product #6, (Andrean Serenity Extract Herbal Supplement), containing new dietary ingredients *Sanguisorba minor* Scopoli and *Perezia coerulescens* Wedd.

21 U.S.C. 350b(a)(2), requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredients do not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that the new dietary ingredients stated above will reasonably be expected to be safe. The information in your submission does not meet the requirements of 21 CFR 190.6(b)(3) because it does not contain a description of the dietary supplements that contain the new dietary ingredients including the level of the new dietary ingredients in the dietary supplements (see 21 CFR 190.6(b)(3)(i)), nor does it describe, in a quantitative manner, the amounts to be consumed daily. The submission contains evidence of history of use and other information that you assert is an adequate basis to conclude that the dietary supplements containing the new dietary ingredients will reasonably be expected to be safe. However, the information in the submission is inadequate to make such a determination (see CFR 190.6(b)(4)). Moreover, the submission provides no explanation or information that enables a determination to be made that the citations in the submission are relevant to determining whether your products, as formulated and at the expected exposure when used as suggested in labeling, would reasonably be expected to be safe.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the products that are subject of your notification, when used under the conditions recommended or suggested in the labeling of your products, will reasonably be expected to be safe. Therefore, your products may be adulterated under 21 U.S.C. 342(f)(1)(B) as dietary supplements that contain the new dietary ingredients specified for which there is inadequate information to provide reasonable assurance that such ingredients do not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Please contact us if you have any questions concerning this matter.

Sincerely yours,

Felicia B. Satchell

Felicia B. Satchell
(Acting) Division Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements

Pre-market Notification

Scientific Name	Common Name
Acicarpha tribuloides	Estrella Kiska
Schkuria pinnata	Canchalagua
Geranium filipes	Chili-chili
Mutisia acuminata	Chinchircoma
Equisetum bogotense	Cola de caballo
Stachys pusilla	Hierba de Cance
Bursera graveolens	Palo Santo
Chuquiraga spinosa	Wamanpinta
Desmodium molliculum	Runa manayupa
Oenothera rosea	Yawar chonca
Perezia coerulescens	Valeriana
Piper alveolatum	Matico
Salvia sagittata	Salvia real
Sanguisorba minor	Pimpinela
Satureja revoluta	Té de Indio
Tessaria integrifolia	Pájaro Bobo

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